IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., FOLDRX PHARMACEUTICALS, LLC, PF PRISM IMB B.V. and WYETH LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No._____
CIPLA LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pfizer Inc.; FoldRx Pharmaceuticals, LLC; PF PRISM IMB B.V.; and Wyeth LLC (referred to collectively herein as "Plaintiffs") file this Complaint for patent infringement against Cipla Limited ("Cipla"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Cipla's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Vyndamax® (tafamidis) 61 mg capsules prior to the expiration of U.S. Patent No. 9,770,441 ("the '441 patent") (attached as Exhibit A).

2. Cipla notified Pfizer by letter dated July 7, 2023 ("Cipla's Notice Letter") that it has submitted to the FDA ANDA No. 218409 ("Cipla's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic tafamidis 61 mg capsules ("Cipla's ANDA Product") prior to the expiration of the '441 patent.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

4. Plaintiff FoldRx Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 66 Hudson Boulevard East, New York, NY 10001. FoldRx Pharmaceuticals, LLC is the holder of New Drug Application ("NDA") No. 212161 for the manufacture and sale of tafamidis 61 mg capsules, which has been approved by the FDA. FoldRx Pharmaceuticals, LLC is a wholly owned subsidiary of Pfizer Inc.

5. Plaintiff PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Cepelle aan den IJessel, the Netherlands.

6. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 66 Hudson Boulevard East, New York, NY 10001.

7. Upon information and belief, defendant Cipla is a corporation organized and existing under the laws of India, with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

8. Upon information and belief, Cipla knows and intends that upon approval of Cipla's ANDA, Cipla will manufacture and directly or indirectly market, sell, and distribute Cipla's ANDA Product throughout the United States, including in Delaware.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Cipla is subject to personal jurisdiction in Delaware because, among other things, Cipla has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Cipla, itself and through its agents develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in continuous and systematic business contacts within the State of Delaware.

11. Upon information and belief, if Cipla's ANDA is approved, Cipla will directly or indirectly manufacture, market, sell, and/or distribute Cipla's ANDA Product within the United States, including in Delaware, consistent with Cipla's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Cipla regularly does business in Delaware, and its practices with other generic products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Cipla's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Cipla's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of the activities would have a substantial effect within Delaware and would constitute infringement of the '441 patent in the event that Cipla's ANDA Product is approved before the '441 patent expires.

12. Upon information and belief, Cipla derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Cipla and/or for which Cipla is the named applicant on approved ANDAs. Upon information and belief, various products for which Cipla is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

13. Alternatively, the Court may exercise personal jurisdiction over Cipla pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Cipla would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Cipla has sufficient contacts with the United States as a whole, including but not limited to filing an ANDA with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that the Court's exercise of jurisdiction over Cipla satisfies due process.

14. Venue is proper in this district as to Cipla pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cipla is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

15. Plaintiff FoldRx Pharmaceuticals, LLC is the holder of New Drug Application No. 212161 for Vyndamax®, which has been approved by the FDA.

16. Vyndamax® is approved for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

17. Vyndamax® contains tafamidis as its active ingredient.

18. Cipla's ANDA Product is a generic version of Vyndamax®.

19. Cipla's Notice Letter purported to include an "Offer of Confidential Access" to Plaintiffs to portions Cipla's ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

20. On July 26, 2023, counsel for Plaintiffs sent a letter to counsel for Cipla attempting to negotiate access to Cipla's internal documents, data, and/or samples relevant to infringement based on reasonable confidentiality terms. Counsel for Cipla did not accept Plaintiffs' proposal.

21. Plaintiffs are filing this Complaint within forty-five days of receipt of Cipla's Notice Letter.

COUNT I – INFRINGEMENT OF THE '441 PATENT

22. Plaintiffs incorporate each of the preceding paragraphs 1–21 as if fully set forth herein.

23. The '441 patent, titled "CRYSTALLINE SOLID FORMS OF 6-CARBOXY-2(3,5-DICHLOROPHENYL)-BENZOXAZOLE", was duly and legally issued on September 26, 2017.

24. The inventors named on the '441 patent are Kevin Paul Girard, Andrew J. Jensen, and Kris Nicole Jones.

25. Pfizer Inc. is the assignee of the '441 patent.

26. Plaintiffs together own all substantial rights in the '441 patent.

27. Vyndamax® and its use are covered by one or more of claims 1–16 of the '441 patent, and the '441 patent has been listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Vyndamax®.

28. For example, claim 1 of the '441 patent recites:

> A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
> a solid state NMR spectrum comprising 13C chemical shifts

(ppm) at 120.8±0.2 and 127.7±0.2,
a powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6±0.2, and
a Raman spectrum comprising a Raman shift peak (cm-1) at 1292±2.

29. In Cipla's Notice Letter, Cipla notified Plaintiffs of the submission of Cipla's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Cipla's ANDA Product prior to the expiration of the '441 patent.

30. In Cipla's Notice Letter, Cipla also notified Plaintiffs that, as part of its ANDA, Cipla had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '441 patent. Cipla submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '441 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

31. Upon information and belief, Cipla's ANDA Product and the use of Cipla's ANDA Product (including in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product) are covered by one or more of claims 1–16 of the '441 patent.

32. For example, claim 1 of the '441 patent recites:

A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
a solid state NMR spectrum comprising 13C chemical shifts (ppm) at 120.8±0.2 and 127.7±0.2,
a powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6±0.2, and
a Raman spectrum comprising a Raman shift peak (cm-1) at 1292±2.

33. In Cipla's Notice Letter, Cipla states that its ANDA Product contains tafamidis, i.e., 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

34. Upon information and belief, the proposed labeling for Cipla's ANDA Product directs and encourages a method of treating a transthyretin amyloid disease, wherein the transthyretin amyloid disease is familial amyloid cardiomyopathy using Cipla's ANDA Product.

35. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product before the expiration of the '441 patent was an act of infringement of the '441 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Cipla will engage, directly or indirectly, in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of Cipla's ANDA.

37. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product would infringe one or more of claims 1–16 of the '441 patent.

38. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more of claims 1–16 of the '441 patent.

39. Upon information and belief, Cipla plans and intends to, and will, actively induce infringement of the '441 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Cipla's activities will be done with knowledge of the '441 patent and specific intent to infringe that patent.

40. Upon information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '441 patent, that Cipla's ANDA Product is not a staple article or commodity of commerce, and that Cipla's ANDA Product

and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to infringement of the ’441 patent immediately and imminently upon approval of Cipla’s ANDA.

41. Notwithstanding Cipla’s knowledge of the claims of the ’441 patent, Cipla has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Cipla’s ANDA Product with their product labeling following FDA approval of Cipla’s ANDA prior to the expiration of the ’441 patent.

42. The foregoing actions by Cipla constitute and/or will constitute infringement of the ’441 patent; active inducement of infringement of the ’441 patent; and contribution to the infringement by others of the ’441 patent.

43. Upon information and belief, Cipla has acted with full knowledge of the ’441 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’441 patent; active inducement of infringement of the ’441 patent; and/or contribution to the infringement by others of the ’441 patent.

44. Plaintiffs will be substantially and irreparably damaged by infringement of the ’441 patent.

45. Unless Cipla is enjoined from infringing the ’441 patent, actively inducing infringement of the ’441 patent, and contributing to the infringement by other of the ’441 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE ’441 PATENT

46. Plaintiffs incorporate by reference each of the preceding paragraphs 1–45 as if fully set forth herein.

47. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on one hand and Cipla on the other regarding Cipla's infringement, active inducement of infringement, and contribution to the infringement by others of the '441 patent, and/or the validity of the '441 patent.

48. An actual case or controversy exists between Plaintiffs and Cipla with respect to Cipla's liability for infringement of the '441 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Cipla's ANDA Product will infringe, induce infringement, and actively contribute to the infringement of the '441 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that the '441 patent has been infringed under 35 U.S.C. § 271(e)(2) by Cipla's submission to the FDA of Cipla's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, offer for sale, sale or importation of Cipla's ANDA Product, or any other drug product that infringes or the use of which infringes the '441 patent, be not earlier than the expiration dates of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Cipla, and all persons acting in concert with Cipla, from the commercial manufacture, use, sale, offer for sale, or importation in the United States of Cipla's ANDA Product, or any other drug product covered by or whose use

is covered by the '441 patent prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product, or any other drug product covered by or whose use is covered by the '441 patent, prior to the expiration of said patent, will infringe, induce the infringement of, and contribute to the infringement by others of said patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further relief and other relief as this Court may deem just and proper.

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